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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,316	09/25/2001	Toshio Imai	TOYAM77.001AUS	1352

7590 10/04/2004

CHOATE, HALL & STEWART
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BOSTON, MA 02109

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,316

Applicant(s)

IMAI ET AL.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6 25 04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 12-15 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-20 are currently pending.

Election/Restrictions

1. **Claims 1-8 and 12-14 stand withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Paper filed December 1, 2003.

Claims 15 and 17-20 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the Paper filed December 1, 2003.

Accordingly, **claims 9-11 and 16 are the subject of examination** in the present Office Action.

In view of Applicant's amendment filed June 25, 2004, the following ground of rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 9-11 and 16 stand rejected under 35 U.S.C. 102(b)** as being clearly anticipated by U.S. Patent No. 6,013,257 to Pan et al (A on form PTO-892) as evidenced by Hoover et al. (J. Biol. Chem. [2000] 275(30):23187-23193; U on form PTO-892).

It was previously stated: "The claims are drawn to the treatment of an autoimmune disease, specifically multiple sclerosis, using an antibody specific for the CX3C chemokine "fractalkine." It is noted that the protein named herein as "fractalkine" is also commonly known in the art as "neurotactin," as evidenced by Hoover (Abstract in particular). The '257 patent teaches and claims the treatment of multiple sclerosis in a patient with antibodies to human neurotactin, the sequence of which is disclosed in the '257 patent as SEQ ID NO: 4 (column 2, lines 21-31; column 34, line 16 through column 35, line 14 and claims 1-4 in particular). The prior art teaching clearly anticipates the claimed invention."

Applicant's arguments filed June 25, 2004 have been fully considered but they are not persuasive. Applicant has amended the base claim to recite that the antibody is "monoclonal," arguing that the '257

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patent does not teach treatment with a monoclonal antibody that inhibits the binding of the CX3C chemokine fractalkine (neurotactin) to CX3CR1.

As a first matter, the '257 patent teaches the making and use (column 16, line 62 through column 17, line 59; column 5, line 64 through column 6, line 18; column 7, lines 1-4 and claim 4 in particular) of monoclonal antibodies to the full length of fractalkine as well as to fragments thereof. Applicant alleges that the '257 patent teaches only polyclonal antibodies that are reactive with an N-terminal fragment of fractalkine and that these antibodies are cross reactive with CD84, pointing specifically to column 32, lines 32-36 of the '257 patent for support of this position. However, the passage to which Applicant refers was part of an example localizing fractalkine expression in the brain, not treatment of an inflammatory condition. It is noted that Example 7 of the '257 patent (column 34, lines 16-59) exemplifies the use of antibodies raised to the full extra-cellular domain of fractalkine for the inhibition of an animal model of multiple sclerosis (EAE). Furthermore, the '257 patent specifically recites the preferred use of monoclonal antibodies (column 7, lines 1-4 in particular) that do not cross-react with other proteins naturally in the presence of fractalkine (column 6, lines 5-9 in particular). The '257 patent teaches that antibodies to fractalkine are included within the scope of fractalkine antagonists (column 6, lines 11-14 in particular) and therapeutic use of anti-fractalkine antibodies as fractalkine inhibitors (column 7, lines 13-17 in particular) and that inflammation associated with multiple sclerosis can be treated with inhibitors of fractalkine function (column 34, line 60 through column 35, line 14 in particular). Interaction of fractalkine with CX3CR1 is a function of fractalkine and is therefore encompassed by the teachings of the '257 patent.

Conclusion

3. No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
February 17, 2004

Patrick J. Nolan
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

9/29/04